UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,504	07/25/2003	Clark C. Davis	1001.1869101	1503

28075 7590 01/19/2006

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER
ROY, ANURADHA

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,504	DAVIS ET AL.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/9/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *5,9,11-12,15-17,21-24,28-52,54,56-57,& 60-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10,13-14,18-20,25-27,53,55,& 58-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *listed in Other*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: 7/25/2003, 9/22/2003, 9/26/2003, 12/19/2003, 12/22/2003, & 4/8/2004.

DETAILED ACTION

Restrictions

Claims 5, 9, 11-12, 15-17, 21-24, 28-52, 54, 56-57, & 60-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 23, 2005.

It is noted that the preliminary amendments filed on December 17, 2004 were received and reviewed by the Examiner. Upon reviewing preliminary amendments, an additional restriction requirement was made over the telephone. Based on the second restriction requirement, claims 73-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse over the telephone on December 6, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 10, 14, 19-20, 25-27, 53, 55, & 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobsen et al. (US Patent No. 6,579,246).

Regarding claims 1-4 & 6, Jacobsen et al. discloses a medical device for navigation through anatomy, the medical device being a guidewire (500) comprising:

an elongate body (500) having a proximal end (504), a distal end (510), and a longitudinal axis extending at least from the proximal end to the distal end;

a helical first coil (508,532,538) formed from wire having a substantially non-circular cross section and said cross section having a greater dimension in the radial direction than in the axial direction (Figure 17), wherein the first coil (508,532,538) being located at or near said distal end (510), said first coil substantially comprising a substantially radiopaque material (Column 3, 32-34)

a tubular member having a plurality of slots (Column 13, lines 29-34 & Figures 18 & 19) configured to make said tubular member more flexible in bending (Column 2, lines 55-58)

a core wire (501) at least part of said core wire being located inside said tubular member (Figures 13 & 18), at least a portion of said core wire being located inside said first coil (Figure 17).

Regarding claim 7, Jacobsen et al. discloses a medical device configured to be guided to a target location in anatomy, the medical device comprising:

a first tubular member (514) having a proximal end (516) and a distal end (520);

a core wire (501) extending proximally from said first tubular member, said core wire being attached with a joint (516) to said first tubular member at least at said proximal end, said joint comprising: a first coil (538, 510, & Figure 16) circumscribing said core wire, said first coil being at least partially inside said first tubular member (Figure 18), and at least one of solder and adhesive (Column 12, lines 18-19 & 24-30).

Regarding claim 8, Jacobsen et al. discloses a medical device wherein said core wire being metal (Column 9, line 61) and said first coil being metal (Column 4, lines 5-6), said joint comprising solder (516 & Column 12, lines 18-19) attaching said first coil to said core wire and adhesive attaching at least one of said first coil, said core wire, and said solder, to said first tubular member (Column 12, lines 12-34).

With regard to claim 10, Jacobsen discloses the first tubular member comprising a plurality of slots (Column 13, lines 29-34, Figures 18 & 19) formed in said first tubular member (514), at least a plurality of said slots being substantially perpendicular to said axis (Figure 13 & 18), said slots being formed in a plurality of groups, and at least a plurality of said groups (Column 3, lines 8-13 & Column 6, lines 18-21) comprising a plurality of slots at substantially the same location along said axis (514).

Regarding claims 14 & 19, Jacobsen et al. discloses a medical device wherein core wire having a tapered portion (524), said joint (516) being located at least partially within said tapered portion (Figure 14 & 18). Furthermore, Jacobsen et al. discloses the core wire (501) further being attached to said first tubular member at said distal end (520, & Column 10, lines 49-52) of said first tubular member.

Regarding claim 20, Jacobsen et al. discloses core wire further being attached to said first tubular member at least one location intermediate (518) said proximal end (516) and said distal end (520).

Regarding claim 25, Jacobsen et al. discloses a medical device with a stepped core wire (501 & Figure 14) configured to be guided to a target location in anatomy, the medical device comprising:

a tubular member (514) having a proximal end (516) and a distal end (510) and a plurality of slots (Column 13, lines 29-34 & Figures 18 & 19) configured to make said tubular member more flexible in bending;

a core wire (501) having a proximal section (526, 528, & 504) extending proximally from said tubular member, and a distal section (510) located at least partially inside said tubular member, said core wire comprising an abrupt change in cross-sectional dimension (506, 522, & 524) between said proximal section and said distal section; and said core wire (501) being attached to said tubular member (514) at least at said proximal end (528), said proximal end abutting said abrupt change in cross-sectional dimension (524).

Regarding claims 26 & 27, Jacobsen et al. discloses a medical device comprising a coil circumscribing at least a portion of said core wire (Figure 17) and coil being soldered to said core wire (512 & Column 10, lines 12-16), and wherein tubular member being attached at least to said coil with adhesive (Column 12, lines 30-34).

Regarding claim 53, Jacobsen et al. discloses a medical device configured to navigate through anatomy, the medical device comprising:

a tubular member (514) having a proximal end (516), a distal end (510), and a longitudinal axis extending at least from the proximal end to the distal end, the

tubular member comprising a plurality of slots (Column 13, lines 29-34 & Figures 18 & 19) configured to make it more flexible in bending;

a core wire (501) disposed at least partially within said tubular member and extending proximal therefrom, said core wire having a distal tip (510);

a joint (516) attaching said core wire to said tubular member at said proximal end of said tubular member; and at least one piece of radiopaque material (Column 3, 32-34) inside said tubular member, at or adjacent to said distal end (510) of said tubular member.

Regarding claim 55, Jacobsen et al. discloses a medical device, wherein radiopaque material being a helical coil made of wire (Column 3, 32-34) having a substantially non-circular cross section, said wire having a substantially greater dimension in the radial direction than in the axial direction after being formed into said coil (Figure 13).

Furthermore, regarding claims 58 & 59, Jacobsen et al. disclose a medical device, wherein core wire (501) further being attached to said tubular member (514) at said distal tip (510) of said core wire and core wire having at least one abrupt change in cross-sectional dimension, said abrupt change (506, 522, 524) being at or adjacent to said joint (516 & 524).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. in view of Lui (US Publication No. 2002/0010475).

Jacobsen et al. discloses the previously mentioned elements of the medical device. However, Jacobsen et al. does not disclose a medical device, wherein the coil being formed from wire having a wire diameter, and the coil having at least a portion of its length with a pitch of at least 1.5 times the wire diameter. Lui, however, teaches of a medical device having a coil having at least a portion of its length with a pitch of at least 1.5 times the wire diameter [0126]. It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Lui to design a coil with a pitch at least 1.5 times greater than the wire diameter with Jacobsen et al. in order to allow for greater flexibility of the coil through the anatomy.

Additional Claim Rejections - 35 USC § 103

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. in view of Levine et al. (US Publication No. 2003/0009157).

Jacobsen et al. discloses the aforementioned elements of the medical device. However, Jacobsen et al. does not disclose the tubular member having a chamfer. Levine et al., however, discloses a medical device containing a tubular member having chamfer [0153]. It would have been obvious to one having ordinary skill in the art at the time the invention in view of Levine et al. to chamfer the end of a tube with Jacobsen et al. in order to allow for a snug fit with the adjacent portion of the device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Viera (US Patent No. 5,497,785), Corso, Jr. (US Patent No. 5,406,960), and Anderson et al. (US Patent No. 6,428,512) disclose guidewires with slotted tubular members. Additionally, Jacobsen et al. (US Patent No. 6,428,489) further discloses a guidewire system, similar to the one mentioned above.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700